DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421
Telephone: 425-486-8788
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August 27, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-60

Leo R. Palmer, President
Wabi Fishing Company
1218 Conner Way
La Conner, Washington 98257

WARNING LETTER

Dear Mr. Palmer:

We inspected your firm located at 1218 Conner Way, La Conner, Washington, on March 5-6, 2002, and March 11, 2002, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 113-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; and Part 123-Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Larry D. Gilbert, General Manager. These deviations cause your smoked flavored salmon in jars and vacuum packaged smoked salmon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Low-Acid Canned Food and Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations found are as follows:

LACF OBSERVATIONS

1. You must have a temperature chart that agrees with as nearly as possible, but is no higher than, the known accurate mercury-in-glass thermometer during the process time in order to comply with 21 CFR 113.40(a)(2). On March 5, 2002, your temperature chart recorder had a temperature reading of 241°F, whereas the mercury-in-glass thermometer had temperature reading of 240°F.

2. You must check capper efficiency on your glass containers by a measurement of the cold water vacuum in order to comply with 21 CFR 113.60(a)(2). The capper efficiency on the 9 oz. smoked salmon in glass jars produced at your firm are not checked using a cold water vacuum test.

3. You must determine and record with sufficient frequency that the minimum initial temperature of the product is not lower than the minimum initial temperature identified in the scheduled process in order to comply with 21 CFR 113.87(c). The scheduled process called for an initial temperature (IT) of 42 °F while the actual IT was recorded as 40 °F on a daily process record for product code REG201103 on 2/15/02.

4. Your processing and production information must be entered on the record at the time it is observed by the retort operator or other designated person in order to comply with 21 CFR 113.100(a). The Daily Process Records Form for Still Retorts dated April 5, 2001, had not been completed. This record lacked entries for "Actual Time Cook Cycle Off", Actual Process Time", "End Process Mercury (MIG) temperature", "End Process Recorder Temperature", and "Air Pressure Gauge (psi) End Process".

5. Your processing and production records must have a signature or initials as having been completed by the retort operator, or designated person, and reviewed by a representative of the plant management within one working day in order to comply with 21 CFR 113.100(b). The Daily Process Record Forms for Still Retorts dated February 15, 2001, February 16, 2001, April 11, 2001, and May 15, 2001, had no signature or initials of the retort operators who performed the actual process. Also, the reviewer did not date the February 15, 2001, and February 16, 2001 records, and did not sign or initial and date the records for April 11, 2001, and May 15, 2001.

HACCP OBSERVATIONS

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." Your firm's HACCP plan for vacuum packed hot smoked salmon lists a critical limit of "sufficient length of time in brine", at the brining critical control point that is not adequate to control *Clostridium botulinum* toxin production because it does not specify the amount of time your product needs to be submerged in the brine in order to consistently achieve adequate penetration of the brine into your product in order to consistently achieve adequate penetration of the brine into your product in order to control *Clostridium botulinum* toxin production.

2. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." Your firm's HACCP plan for vacuum packed hot smoked

salmon lists a monitoring frequency of "daily" at the cooler storage critical control point that is not adequate to control Clostridium botulinum. For controlling toxin formation during refrigeration, monitoring should be continuous by the instrument itself, with a visual check of the monitoring instrument at least once per day. . Your firm did not follow the monitoring procedure of "full immersion" of product.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for vacuum packed hot smoked salmon at the brining, smoking/cooking, and cooler storage critical control points to control *Clostridium botulinum* and other pathogens does not include how you will address the cause of the deviation and how to prevent it from reoccurring.

4. You must implement the monitoring procedures listed in your HACCP plan for vacuum packed hot smoked, to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedure of "full immersion" of product at the brining critical control point. On March 5, 2002, product was observed floating on the surface of the brine bath, and not fully submerged.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction, and issuance of an order of need to obtain and hold a Temporary Emergency Permit under section 404 of the act and implementing regulations in 21 CFR Part 108.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director